

Response Under 37 CFR §1.116

Expedited Procedure

Examining Group 1637

Application No.: 10/566,223

Paper Dated: December 20, 2010

Response to Office Action dated August 19, 2010

Attorney Docket No.: 4544-060174

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims

Claims 1-116 (Canceled).

Claim 117 (Currently Amended): A method of processing a clinical sample useful for diagnosis of a bacterial infection using a composition comprising Solution 1 comprising Universal Sample Processing (USP) solution comprising Guanidinium Hydrochloride (GuHCl) of concentration ranging between 3-6 M, Tris-Cl of concentration ranging between 40-60 mM of pH ranging between 7.3-7.7, EDTA of concentration ranging between 20-30 mM, Sarcosyl of concentration ranging between 0.3-0.8%, and beta-mercaptoethanol of concentration ranging between 0.1-0.3 M; Solution 2 selected from the group consisting of a) sodium phosphate of concentration ranging between 65 to 70 mM of pH ranging between 6.7 to 6.8; and b) sterile water; and one or more of Solution 3 comprising polysorbate 80 of concentration ranging between 0.03 to 0.08%, Solution A comprising a chelating resin suspension of concentration ranging between 8-12%, Solution B comprising polyoxyethylene phenyl ether of concentration ranging between 0.02 to 0.04%, or Solution C comprising polysorbate 20 of concentration ranging between 0.2-0.4% for isolating DNA, said method comprising steps of:

- (a) obtaining the clinical sample,
- (b) mixing 1.5 to 2 volumes of Solution 1 with the sample,
- (c) homogenizing the sample while avoiding frothing,
- (d) adding Solution 2 to the homogenate followed by centrifugation to obtain a pellet,
- (e) washing the pellet with Solution 1,
- (f) washing the Solution 1-washed pellet with water, and
- (g) resuspending the water-washed mycobacterial pellet in one or more of Solution 3, Solution A, Solution B, and/or Solution C to obtain a processed sample for diagnosis, and

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(h) obtaining viable mycobacteria.

Claim 118 (Previously Presented): The method as claimed in claim 117, wherein homogenizing is conducted for a time duration of 20-120 seconds.

Claim 119 (Previously Presented): The method as claimed in claim 117, wherein the processing is completed in a total time duration ranging between 1-2 hours.

Claim 120 (Previously Presented): The method as claimed in claim 117, wherein Guanidinium Hydrochloride is present in a concentration of about 4 M and beta-mercaptoethanol in a concentration of about 0.1 M in the Universal Sample Processing (USP) solution for processing samples for culture and smear, said Guanidinium Hydrochloride being present in a concentration of about 5 M and said beta-mercaptoethanol in a concentration of between 0.1–0.2M for processing of samples for culture, smear and PCR, and said Guanidinium Hydrochloride being present in a concentration of 6 M and said beta-mercaptoethanol present in a concentration of about 0.2 M for samples processed for smear and PCR.

Claim 121-123 (Canceled).

Claim 124 (Previously Presented): The method as claimed in claim 117, wherein PCR-amplifiable mycobacterial DNA and RNA can be obtained through lysis by boiling in presence of Solution 3 or by adding 0.01-0.1% polyoxyethylene phenyl ether.

Claim 125 (cancelled).

Claim 126 (Previously Presented): The method as claimed in claim 117, wherein samples are stored at about -20°C for up to 2 months and can be processed for PCR, smear-microscopy and culture.

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Claim 127 (Previously Presented): The method as claimed in claim 117 further comprising amplifying at least a fragment of a *devR* gene positioned between a first set of primers: devRf2 and devRr2, or a second set of primers: devRf3 and devRr3.

Claim 128 (Previously Presented): The method as claimed in claim 117, wherein a devRf2 primer and a devRr2 primer amplify a 308 bp fragment of gene *devR* of microbe *Mycobacterium tuberculosis*, wherein the amplification of a 308 bp fragment indicates the presence of *M. tuberculosis* in the sample.

Claim 129 (Previously Presented): The method as claimed in claim 117, wherein a devRf3 primer and a devRr3 primer amplify a 164 bp fragment of the *devR* gene of *Mycobacterium tuberculosis*, wherein the amplification of a 164 bp fragment indicates the presence of *M. tuberculosis* in the sample.

Claim 130 (Withdrawn): A kit useful in processing clinical samples according to the method of claim 117, said kit comprising solution 1 consisting of Universal Sample Processing (USP) solution (composed of Guanidinium Hydrochloride (GuHCl) of concentration ranging between 3-6 M, Tris-Cl of concentration ranging between 40-60 mM of pH ranging between 7.3-7.7, EDTA of concentration ranging between 20-30 mM, Sarcosyl of concentration ranging between 0.3-0.8%, beta-mercaptoethanol of concentration ranging between 0.1-0.3 M), Solution 2 consisting of Sodium phosphate of concentration ranging between 65 to 70 mM of pH ranging between 6.7 to 6.8 (optionally can be replaced with water), Solution 3 consisting of Tween 80 of concentration ranging between 0.03 to 0.08%, Solution A comprising of Chelex 100 suspension of concentration ranging between 8-12%, Solution B consisting of Triton X-100 of concentration ranging between 0.02-0.04%, and Solution C consisting of Tween 20 of concentration ranging between 0.2 to 0.4, optionally two sets of primers with devRf2 and devRr2 of SEQ ID No. 1 and SEQ ID No. 2 respectively, and primers devRf3, and devRr3 of SEQ ID No. 3, and SEQ ID No. 4 respectively.

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Claim 131 (Withdrawn): The kit as claimed in claim 130, wherein Guanidinium Hydrochloride is present in a concentration of about 4 M and beta-mercaptoethanol in a concentration of about 0.1 M in the Universal Sample Processing (USP) solution for processing sample cultures for smear, said Guanidinium Hydrochloride being present in a concentration of about 5 M and said beta-mercaptoethanol in a concentration of between 0.1–0.2 M for processing of samples for culture, smear and PCR, and said Guanidinium Hydrochloride being present in a concentration of 6 M and said beta-mercaptoethanol present in a concentration of about 0.2 M for samples processed for smear and PCR.

Claim 132 (Withdrawn): The kit as claimed in claim 130, wherein the composition comprises solution 1 consisting of Universal Sample Processing (USP) solution, Solution 2 consisting of Sodium phosphate of concentration ranging between 65 to 70 mM of pH ranging 6.7 to 6.8, Solution 3 consisting Tween 80 of concentration ranging between 0.03 to 0.08%, Solution A comprising Chelex 100 suspension of concentration ranging between 8-12%, and Solution B consisting of Triton X-100 of concentration ranging between 0.02-0.04%, and Solution C consisting of Tween 20 of concentration ranging between 0.2-0.4%.

Claims 133-135 (Canceled).